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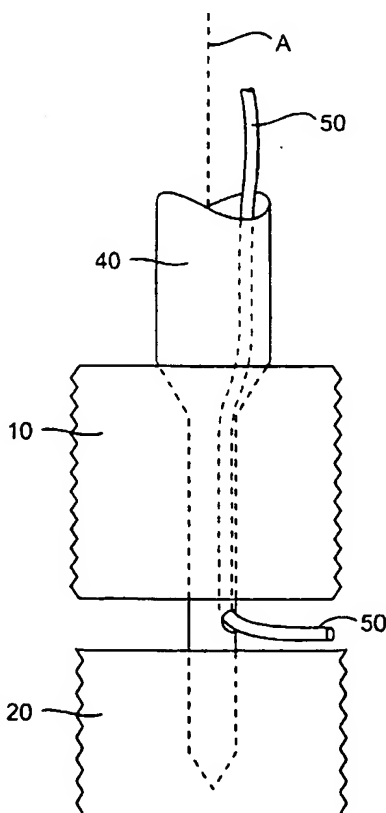
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[Continued on next page]

(54) Title: SYSTEMS FOR SECURING FACET JOINTS TOGETHER



(57) Abstract: This invention is a system for securing first, and second opposing facet joints (10, 20) together, comprising a cannulated drill (40) having a side opening (42), an extending member (50) received within the cannula of the cannulated drill, the extendible member (50) having a distal end which passes out of the side opening in a direction radially outwards from the axis of the cannulated drill as the extendible member is advanced distally through the cannula of the drill. The drill can be rotated such that the extendible member ablates opposite contacting surfaces of first, second facet joints promoting fusion between the first, and second facet joints. A facet screw (30) passing through a hole drilled by the cannulated drill through the first facet joint into the second facet joint is tightened into position to immobilize the first, and second facet joints together.

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SYSTEMS FOR SECURING FACET JOINTS TOGETHER

CROSS-REFERENCES TO RELATED APPLICATIONS

The present application is a regular patent application of and claims the
5 benefit of priority from U.S. Patent Application Serial Nos. 60/167,189 filed November
23, 1999 and 60/129,703 filed April 16, 1999, the full disclosures of which are
incorporated herein by reference.

TECHNICAL FIELD

The present invention relates in general to spinal fixation systems and in
10 particular to facet screw systems for securing adjacent facet joints together.

BACKGROUND OF THE INVENTION

Facet screws are used to secure a patient's facet joints together, thus
preventing relative movement between adjacent facet joints. Such facet screws are
15 typically used during various spinal surgery procedures such as discectomy with posterior
instability; degenerative disc disease; degenerative joint disease in the facet joint; and
general instability, both to prevent relative movement of the facet joints (thus promoting
arthrodesis) and to provide support and stability to the vertebral level (thus promoting
arthrodesis).

20 Other benefits of facet joint screws are that they can be used to stabilize
the spine in lieu of more expensive and surgically time consuming instrumentation, for
example, pedicle screw systems.

A common disadvantage with existing facet screw systems are that they
must be used in conjunction with other stabilization systems, for example, anterior strut
25 grafts or other inorganic implants, to provide sufficient stability to the patient's vertebrae
after surgery and also that they require a difficult surgical procedure to safely place them.

SUMMARY OF THE INVENTION

The present invention provides systems for securing a pair of facet joints
30 together. An advantage of the present invention is that by immobilizing opposing adjacent
facet joints with respect to one another it provides stability for vertebral arthrodesis, as is
desired, for example, after a medical procedure such as a discectomy with fusion.

In accordance with the present invention, a system is provided to position a facet screw to secure a patient's opposite adjacent first and second facet joints together, and to promote fusion therebetween.

5 In a preferred aspect, the facet screw is positioned to secure together the inferior articular process of the first facet joint and the superior articular process of the second facet joint, with the facet screw positioned to pass from a posterior approach through the first facet joint toward the pedicle of the second facet joint. This embodiment is called the transfacet approach. Other approaches for facet screw placement are also contemplated (i.e. the translaminar approach).

10 In a preferred aspect of the present invention, the contacting surfaces of the adjacent facet joints are ablated (to promote fusion) prior to the facet screw being inserted (to securely hold the facet joints together). An advantage of the present system of ablation is that it utilizes the natural healing response of the facet bones, where the ablated contacting surfaces of the facet joints will tend to fuse together after such
15 ablation.

In a preferred aspect of the present invention, the opposite contacting surfaces of the facet joints are ablated by an extending member which protrudes radially outwardly from a drill (at a location between the opposite contacting surfaces). Preferably, the drill from which the extending member protrudes is the same drill which
20 is used to drill a hole for the facet screw placement.

Most preferably, the extending member comprises a flexible wire which is received in a cannulated passageway in the drill. In this preferred aspect of the invention, the drill preferably has a side hole and the extending member (i.e.: the flexible wire) is advanced distally through a cannulated passage in the drill such that the wire's distal end
25 protrudes radially outwardly through the side hole in the drill.

In this aspect of the invention, the drill is advanced through the first facet joint and into the second facet joint to a depth such that its side hole is positioned between the opposite contacting surfaces of the first and second facet joints.

Thereafter, the extending member is advanced to protrude outwardly to a
30 desired radial distance from the drill, such that further rotation of the drill will cause the extending member to rotate in a circular path around the drill, thereby ablating a rather large surface area of the opposite contacting surfaces of the first and second facet joints. The specific size of the ablated region on each of the opposite contacting surfaces on the

first and second facet joints will depend upon the length to which the distal end of the extending member is advanced to protrude outwardly from the drill.

Accordingly, an advantage of the present drill being adapted such that an extending member can be deployed therefrom (e.g.: through a side hole therein) is that a rather large area of the facet joint surfaces can be accessed and thereby ablated, yet requiring only a standard sized drill hole as would typically be used to insert a standard facet screw.

In optional aspects of the present invention, the facet screw is introduced into the patient in a cannulated posterior approach. In such aspects of the invention, the drill may be advanced through an operating cannula such that a distal end of the drill commences drilling at a posterior point on the inferior articular process of the first facet joint.

In yet another optional aspect of the present invention, the drill itself is dimensioned (i.e.: tapered) to drill a countersink into the first facet joint, such that the head of the facet screw can be received substantially flush against the first facet joint. Consequently, the head of the facet screw can be positioned out of the way of surrounding tissues.

In yet another optional aspect of the present invention, the drill (and the facet screw) are positioned in a preferred posterior approach into the patient by way of a surgical guidance platform, with the drill and the facet screw being sequentially advanced through an operating cannula which is supported by the surgical guidance platform.

In yet another optional aspect of the present invention, the extending member is advanced into the facet joint between the opposing contact surfaces of the first and second facet joints by means of a cannulated delivery device (rather than a drill).

In an optional preferred aspect of the present invention, the extendible member may comprise a wire made of a shape memory metal, such as Nitinol, but is not so limited as other suitable materials may instead be used.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a top view of first and second facet joints being held together by a facet screw, showing a preferred angle of placement of the facet screw.

Fig. 2A is a side (anterior-posterior) view of first and second facet joints being held together by a facet screw, showing a preferred angle of placement of the facet screw.

Fig. 2B is a side (lateral) view of first and second facet joints being held together by a facet screw, showing a preferred angle of placement of the facet screw.

Fig. 3 is an illustration of a drill being advanced towards a first facet joint.

Fig. 4 is an illustration of a drill being advanced through a first facet joint,
5 and into a second facet joint, showing the position of a side hole in the drill with respect to the first and second facet joints.

Fig. 5 is an illustration of a an extending member being advanced through a cannulated passageway in the drill such that the distal end of the extending member passes out through the side hole in the drill.

10 Fig. 6 is an illustration of the rotation of the drill and extending member (with the first facet joint removed for clarity).

Fig. 7 is an illustration of the placement of the facet screw, passing through the first facet joint and into the second facet joint.

Fig. 8 is an illustration of the placement of the facet screw using a surgical
15 guideframe.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

In accordance with the present invention, a pair of opposing facet joints may be secured together by a system comprising a facet screw. Referring to Figs. 1, 2A
20 and 2B, first facet joints 10 and second facet joints 20 are secured together by a pair of facet screws 30. As illustrated, facet screws 30 are positioned in a posterior approach with respect to the patient, however, other approaches into the patient are also contemplated. As illustrated, first facet joint 10 preferably comprises a patient's inferior articular process and second facet joint 20 comprises a patient's superior articular process.

25 Figs. 3 to 7 show sequential steps in placing facet screw 30 such that it passes through first facet joint 10 and into second facet joint 20 (as was shown in Figs. 1, 2A and 2B). When tightened into position, facet screw 30 will immobilize first facet joint 10 and second facet joint 20 together.

Referring to Fig. 3, a cannulated drill 40 is first positioned to drill a hole
30 for the facet screw. Placement of cannulated drill 40 in a preferred orientation (for example, in a preferred posterior approach) with respect to the patient can be achieved by using a surgical guidance platform such as the platform set forth in co-pending U.S. Patent Application No. 09/326,739 filed June 4, 1999, incorporated herein by reference in its entirety.

Drill 40 is rotated in direction R and advanced distally in direction D such that it drills a hole through first facet joint 10 and into second facet joint 20, as illustrated in Fig. 4. Drill 40 has a side opening 42 which is then preferably positioned between adjacent opposite contacting surfaces 11 and 21 of respective facet joints 10 and 20, as shown.

Thereafter, as shown in Fig. 5, an extending member 50, which may preferably comprise a flexible wire, is advanced distally in direction D through a cannulated passageway in drill 40 such that a distal end of extending member 50 protrudes out through side hole 42, and projects radially outward from the central longitudinal axis A of drill 40, as shown.

As shown in Fig. 6, (with first facet joint 10 removed for clarity), drill 40 is then rotated with extending member 50 protruding radially therefrom. As such, extending member 50 will ablate adjacent opposite contacting surfaces 11 and 21 of respective facet joints 10 and 20. For example, the flexible wire extending member 50 will ablate region 12 (shown bound by dotted lines) on top of surface 11. Similarly, extending member 50 will also ablate a corresponding region of surface 21.

The ablation of such large circular regions of opposite contacting surfaces 11 and 21 will tend to promote a healing response in the bony tissue of the facet joints, such that first facet joint 10 and second facet joint 20 will then tend to fuse together over time. As shown in Fig. 7, drill 40 is then removed and facet screw 30 is then advanced through the hole which had been drilled by drill 40. When tightly screwed into position, relative movement between first facet joint 10 and second facet joint 20 will be effectively inhibited. This, coupled with the fusion between first facet joint 10 and second facet joint 20 promoted by ablation of their contacting surfaces, will provide an effective system for securing a patient's opposing first and second facet joints together.

In an optional preferred aspect of the present invention, drill 40 is dimensioned with a tapered portion 43 along its length such that drill 40 cuts a countersink in first facet joint 10. As shown in Fig. 7, the countersink cut by drill 40 is preferably dimensioned such that head 32 of facet screw 30 can be received therein. Head 32 can thus be positioned to be received generally flat against the surface of first facet joint 10, such that head 32 does not project outwardly into the surrounding tissue.

Fig. 8 is an illustration of the placement of facet screw 30 such that it fastens first facet joint 10 and second facet joint 20 together. Facet screw 30 (and drill 40, not shown) are oriented in a preferred posterolateral approach with respect to patient P.

Specifically an operating cannula 60 is suspended from a surgical guidance platform 70 such that it can be rotated to desired positions by being rotated in direction R2 and translated to various positions in direction D2. An example of a suitable surgical guidance platform is found in co-pending U.S. Patent Application No. 09/326,739 filed June 4, 5 1999, previously incorporated by reference.

While the exemplary embodiments have been described in some detail, by way of example and for clarity of understanding, a variety changes, adaptations, and modifications will be obvious to those of skill in the art. Hence, the scope of the present invention is limited solely by the appended claims.

10

WHAT IS CLAIMED IS:

- 1 1. A method of securing a patient's first and second opposing facet
2 joints together, comprising:
3 drilling a hole through the first facet joint and into the second facet joint;
4 ablating contacting surfaces disposed between each of the first and second
5 facet joints; and
6 inserting a facet screw into the hole.
- 1 2. The method of claim 1, wherein, the ablating is performed by,
2 extending an extendible member radially outwards from a drill at a
3 location between the contacting surfaces; and
4 rotating the drill such that the extendible member moves in a circular path
5 across portions of the contacting surfaces.
- 1 3. The method of claim 2, wherein extending an extendible member
2 radially outwards from a drill comprises,
3 distally advancing an ablation wire received within a cannulated
4 passageway in the drill such that a distal end of the ablation wire extends outwardly
5 through a side hole in a rotating drill.
- 1 4. The method of claim 1, wherein, the hole is drilled in a
2 posterolateral approach through the first facet joint and into the second facet joint.
- 1 5. The method of claim 4, further comprising:
2 positioning an operating cannula in a posterolateral approach with respect
3 to the patient; and
4 advancing a drill through the operating cannula such that a distal end of
5 the drill commences drilling at a posterium of the inferior articular process of the first
6 facet joint.
- 1 6. The method of claim 5, wherein, a surgical guideframe is used to
2 position the operating cannula in the posterolateral approach.
- 1 7. The method of claim 1, further comprising:
2 drilling a countersink into the first facet joint.

1 8. A system for securing first and second opposing facet joints
2 together, comprising:
3 a cannulated drill having a side opening; and
4 an extendible member slidably received within the cannula of the
5 cannulated drill, the extendible member being positionable such that its distal end passes
6 out of the side opening in the cannulated drill in a direction radially outwards from the
7 axis of the cannulated drill as the extendible member is advanced distally through the
8 cannula of the drill.

1 9. The system of claim 8, wherein,
2 the cannulated drill has an outer diameter which is tapered to drill a
3 countersink in the first facet joint.

1 10. The system of claim 8, wherein the extendible member is a flexible
2 wire.

1 11. The system of claim 10, wherein the wire is made of a shape
2 memory metal.

1 12. The system of claim 8, further comprising:
2 a facet screw dimensioned to be received within a hold drilled by the
3 cannulated drill.

1 13. The system of claim 8, further comprising:
2 an operating cannula dimensioned to receive the cannulated drill
3 therethrough.

1 14. The system of claim 13, further comprising:
2 a surgical guideframe for positioning and supporting the operating cannula
3 in a posterolateral approach.

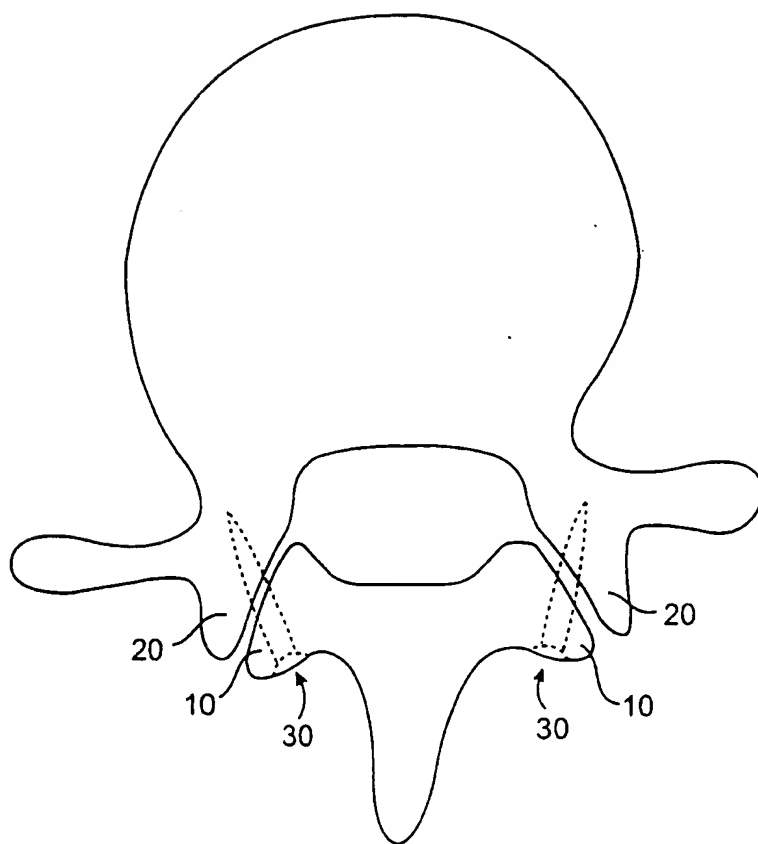


FIG. 1

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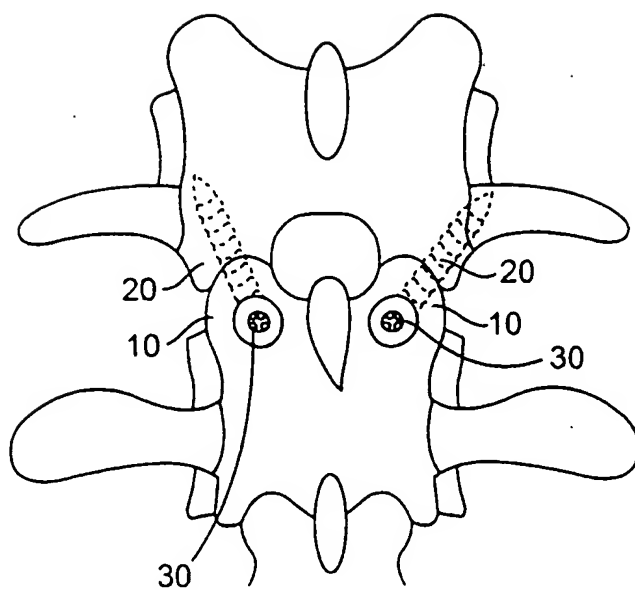


FIG. 2A

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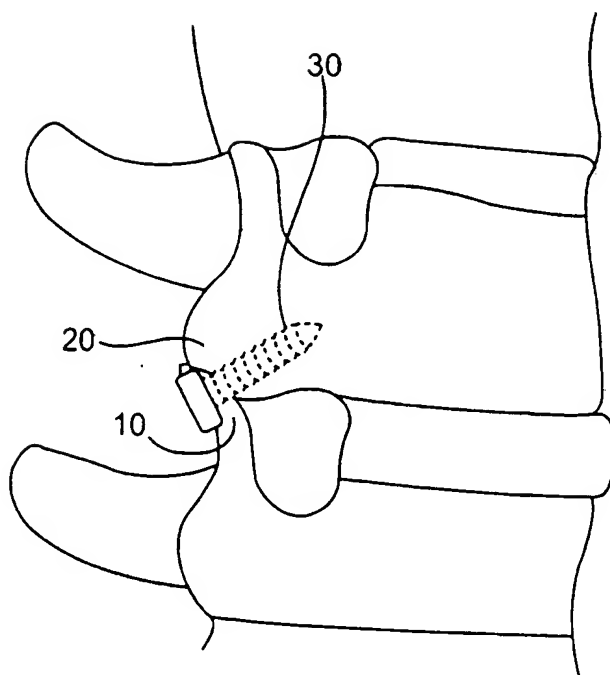


FIG. 2B

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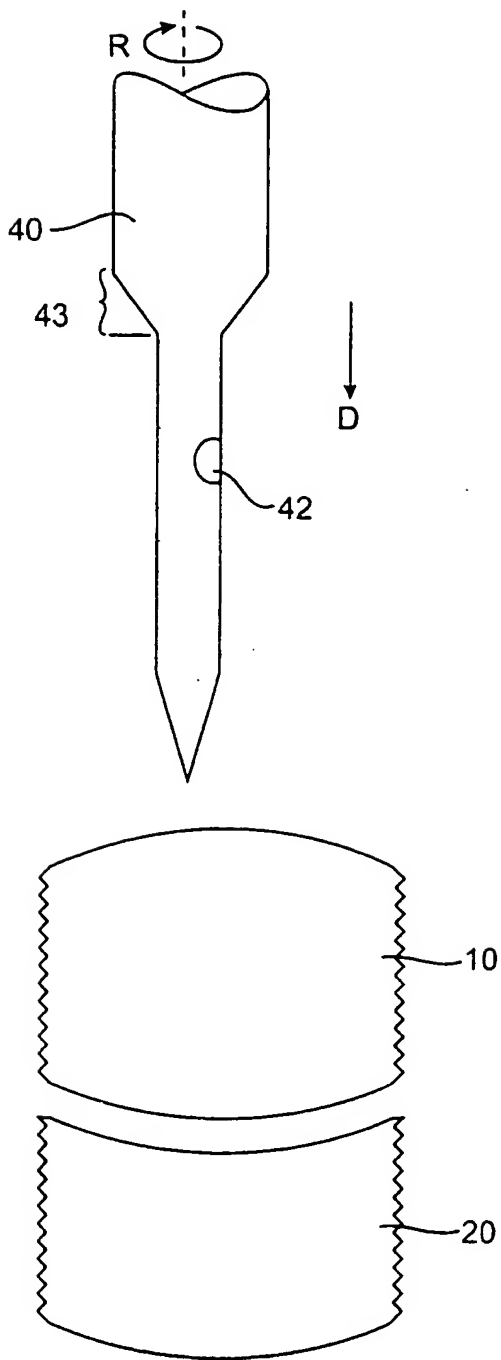


FIG. 3

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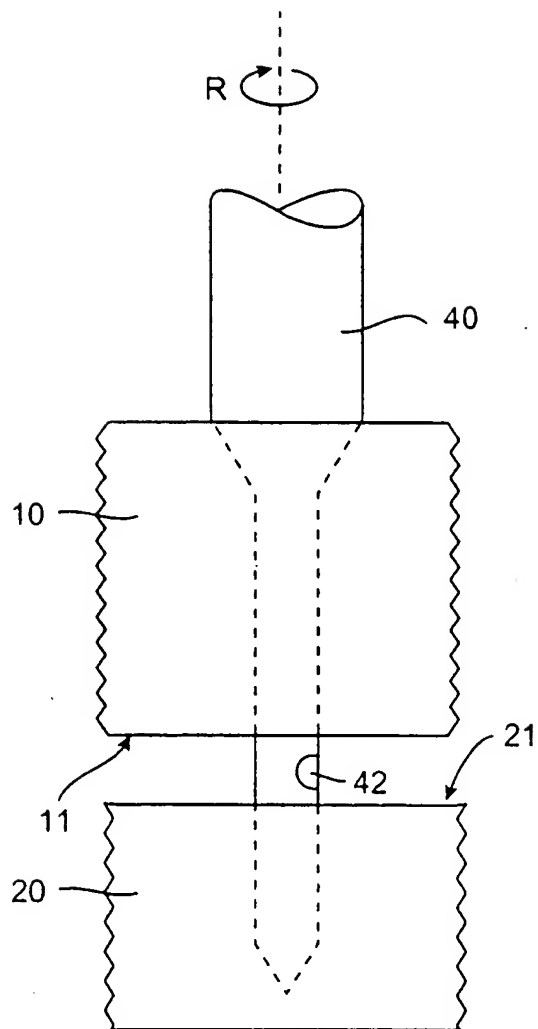


FIG. 4

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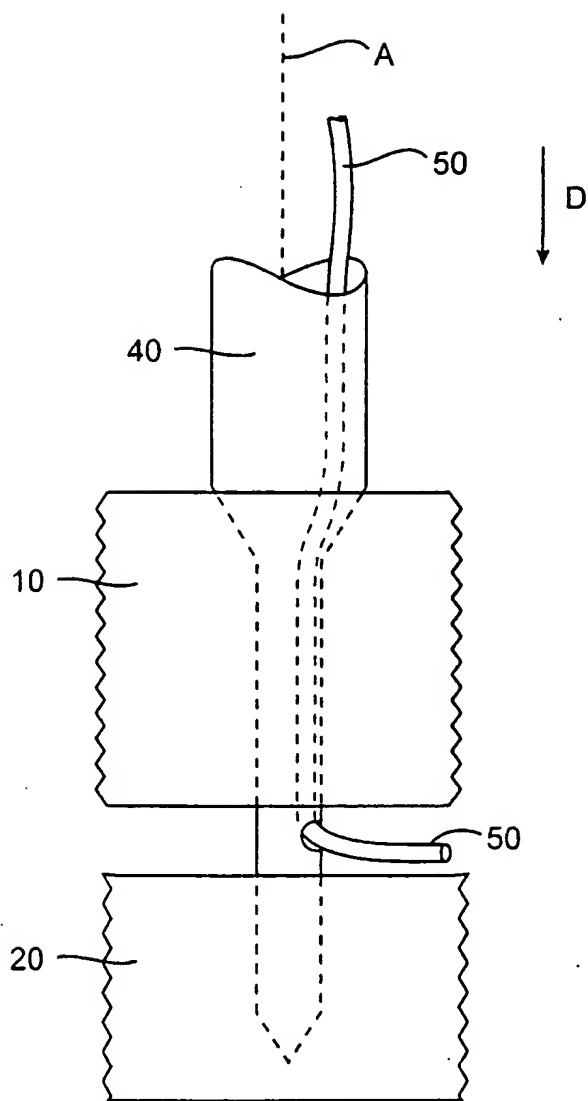


FIG. 5

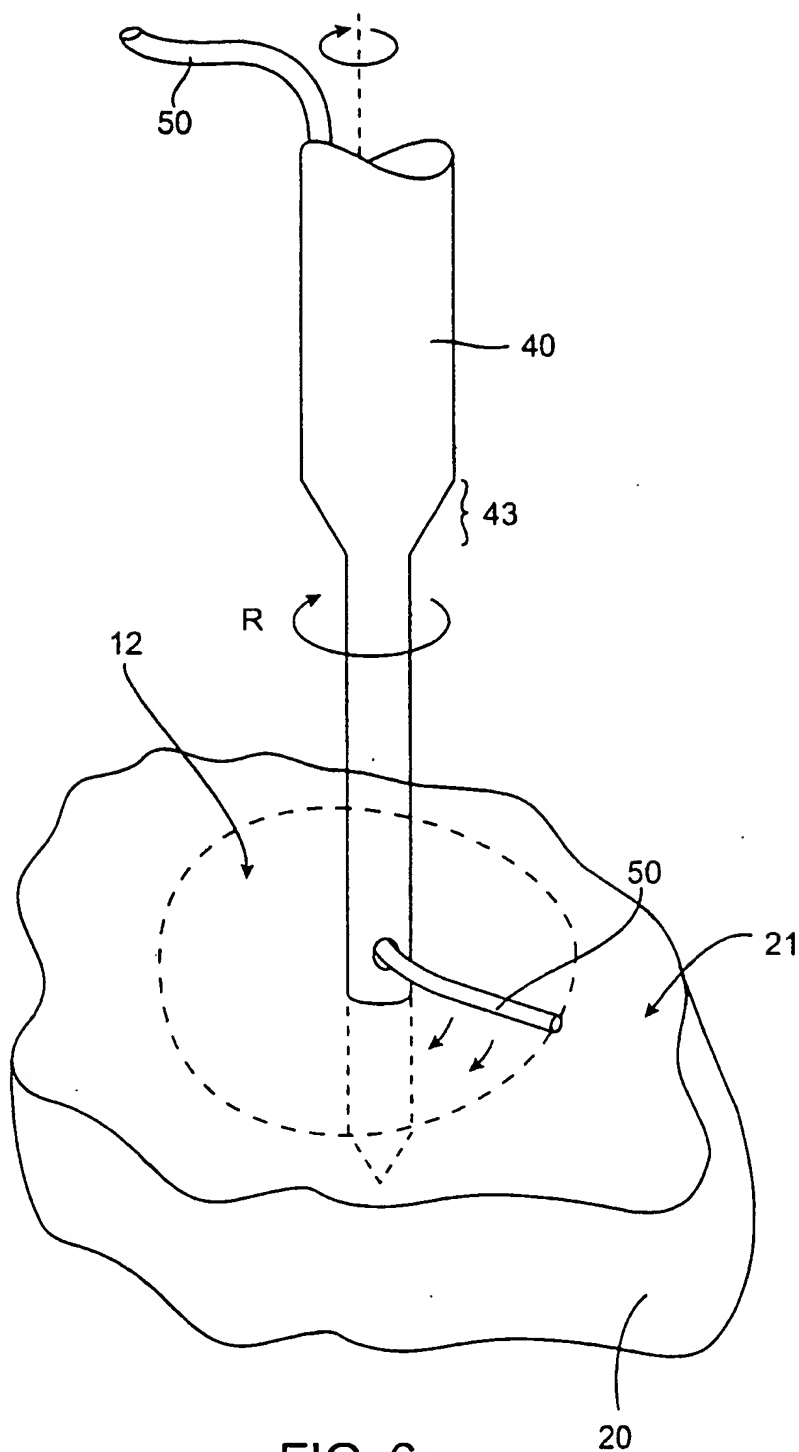


FIG. 6

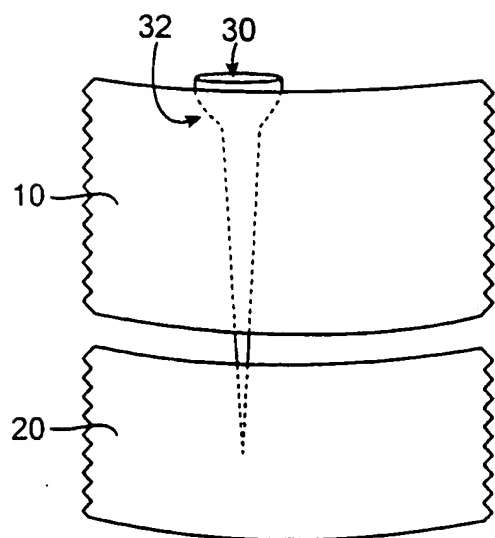


FIG. 7

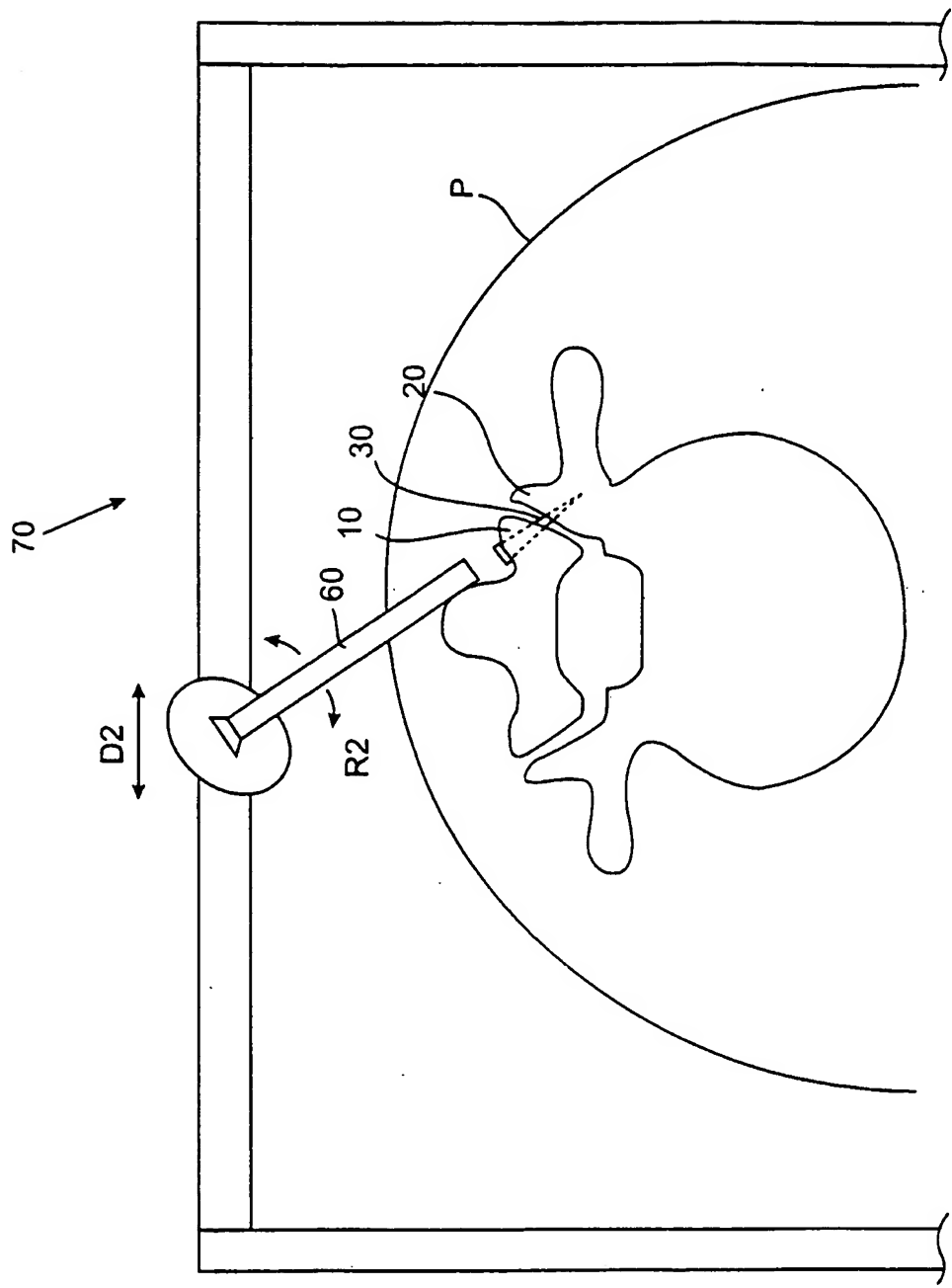


FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/10000

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 17/16. 70

US CL : 606/61. 80

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/61. 80

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WEST

Search Terms: cannula, drill, spine, spinal, hole, wire

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,728,097 A (MATHEWS) 17 March 1998, entire document.	1-14
Y	US 5,562,735 A (MARGULIES) 08 October 1996, entire document.	1-14
Y	US 5,591,170 A (SPIEVACK et al.) 07 January 1997, entire document.	1-14
Y	US 4,541,423 A (BARBER) 17 September 1985, entire document.	1-14
Y	US 4,907,577 A (WU) 13 March 1990, entire document.	1-14
Y	US 4,781,181 A (TANGUY) 01 November 1988, entire document.	1-14

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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Date of the actual completion of the international search

04 AUGUST 2000

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INTERNATIONAL SEARCH REPORT

International application No.
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A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 17/16. 70

US CL : 606/61. 80

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

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INTERNATIONAL SEARCH REPORT

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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Y	US 5,702,452 A (ARGENSON et al.) 30 December 1997, entire document.	1-14
Y	US 5,476,463 A (BOACHIE-ADJEI et al.) 19 December 1995, entire document.	1-14
Y	US 5,470,333 A (RAY) 28 November 1995, entire document.	1-14
A	US 5,713,900 A (BENZEI et al.) 03 February 1998, entire document.	1-14

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